

And C37 wt
--3. (amended) [The monoclonal antibody of claim 1 which inhibits growth of tumor cells which express PSCA] A monoclonal antibody which recognizes and binds the C-terminal portion of the Prostate Stem Cell Antigen comprising amino acids 85 through 123. --

B3 wt
--4. (amended) The monoclonal antibody of claim 1, 2, or 3, which is internalized by the cell. --

--5. (amended) [A] The monoclonal antibody of claim 1, 2 or 3 comprising murine antigen binding region residues and human antibody residues. --

--6. (amended) [A] The monoclonal antibody of claim 1, 2 or 3 which is a human antibody. --

--9. (amended) A hybridoma producing the [a] monoclonal antibody of claim 1, 2, or 3 [8]. --

B3
--10. (amended) A recombinant protein comprising the antigen binding region of a monoclonal antibody of claim 1, 2, or 3 [8]. --

--11. (amended) An Fab, F(ab')₂ or Fv fragment of a monoclonal antibody of claim 1, 2, or 3 [or 8]. --

REMARKS

Claim 8 has been cancelled herein. Claims 1-6 and 9-11 are pending. Applicants amended claims 1-6 and 9-11 herein.

Support for amended claim 1 can be found in the originally-filed application at page 29, lines 14-19; page 84, lines 23-30; and Figures 15 and 49.

Support for amended claim 2 can be found in the originally-filed application at page 29, lines 14-19; page 84, lines 23-30; and Figures 15 and 49.

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Support for amended claim 3 can be found in the originally-filed application at page 29, lines 14-19; page 84, lines 23-30; and Figures 15 and 49.

Support for amended claim 4 can be found in the originally-filed application at page 26, lines 20-22; and page 29, lines 4-9.

Support for amended claim 5 can be found in the originally-filed application at page 21, line 11; page 25, lines 1-30; and page 26, lines 1-4.

Support for amended claim 6 can be found in the originally-filed application at page 21, line 11; and page 28, lines 20-29.

Support for amended claim 9 can be found in the originally-filed application at page 24, lines 21-28; and page 81, lines 23-28.

Support for amended claim 10 can be found in the originally-filed application at page 21, lines 13-16; page 29, lines 21-25; and page 31, lines 14-19.

Support for amended claim 11 can be found in the originally-filed application at page 21, lines 13-16; page 21, line 30; page 22, lines 1-2; and page 22, line 23.

The amendment of claims 1-6 and 9-11 are supported in the originally filed application and do not involve new matter. Entry of these changes is requested.

The changes to the specification are merely to add the sequence listing numbers for the respective sequences and does not involve new matter. Entry of these changes is requested.

SEQUENCE LISTINGS

The Examiner is requiring a substitute paper copy and a computer readable form of the Sequence Listing, which applicants provide herein.

DRAWING REQUIREMENTS

The Examiner has objected to the drawings. Applicants will attend to this matter.

RESTRICTION REQUIREMENT

In the Office Action, the Patent Office is requiring restriction under 35 U.S.C. §121 to one of the following Groups of inventions:

- Group 1: Claims 1-6 and 8-11 are directed to antibodies and hybridomas which produce the antibodies;
- Group 2: Claim 7 is directed to transgenic animals producing an antibody;
- Group 3: Claims 12-17 are directed to immunoconjugates;
- Group 4: Claims 18-27, 34-36 in part, and 28-29 are directed to methods for inhibiting the growth of prostate carcinoma cells, comprising administering an antibody which binds the extracellular domain of PSCA;
- Group 5: Claims 18-27, 34-36 in part, and 30-31 are directed methods for inhibiting the growth of human bladder carcinoma cells and metastasis of human bladder carcinoma cells, comprising administering an antibody which binds the extracellular domain of PSCA;
- Group 6: Claims 18-27, 34-36 in part, and 32-33 are directed to methods for inhibiting the growth of human pancreatic carcinoma cells and metastasis of human pancreatic carcinoma cells, comprising administering an antibody which binds the extracellular domain of PSCA;
- Group 7: Claims 37-41 and 65 are directed to methods for inhibiting the growth of tumor cells expressing PSCA, comprising administering a combination of antibodies which binds with PSCA;

- Group 8: Claims 42-51 and 58-61 in part, and 52-53, and 63 are directed to methods for treating a subject having a cancer, comprising administering an antibody which binds the extracellular domain of PSCA, wherein the tumor cells are human prostate carcinoma and metastasis of a human prostate carcinoma.
- Group 9: Claims 42-51, and 58-61 in part, and 54-55, and 63 are directed to methods for treating a subject susceptible to or having a cancer, comprising administering an antibody which binds the extracellular domain of PSCA, wherein the tumor cells are human bladder carcinoma and metastasis of a human bladder carcinoma.
- Group 10: Claims 42-51, and 58-61 in part, and 56-57, and 64 are directed to a method of treating a subject susceptible to or having a cancer, comprising administering an antibody which binds the extracellular domain of PSCA, wherein the tumor cells are human pancreatic carcinoma and metastasis of a human pancreatic carcinoma.
- Group 11: Claims 66-68 are directed to methods for selectively inhibiting the growth of a cell expressing PSCA, comprising reacting an immunoconjugate or immunotoxin to the cell.

TRAVERSAL

Applicants hereby confirm election of the invention of Group 1 with traverse. Applicants have cancelled claim 8 and amended claims 1-6 and 9-11, the claims in Group 1, herein.

Reconsideration of the Restriction Requirement is requested for the following reasons:

Applicants point out that under MPEP §803, there are two criteria for a proper requirement for restriction, namely: (1) the invention must be independent and distinct; AND (2) there must be serious burden on the Examiner for restriction to be required.

Applicants respectfully contend that the first requirement of §803 has not been met, since the claims of Group 3 depend, directly or indirectly, upon the claims of Group 1. Therefore, the invention in Groups 1 and 3 are not independent. Accordingly, the criteria for requiring the restriction has not been met.

The Office states that in the subject application, the monoclonal antibodies of Group 1 and the immunoconjugates of Group 3 are structurally, physically, and chemically different from each other. Applicants contend that immunoconjugate is generated by producing the monoclonal antibody and then linking the monoclonal antibody with a molecule, such as a cytotoxic molecule. Furthermore, the Office states that the monoclonal antibodies of Group 1 are classified in class 530, subclass 388.85 and the immunoconjugates of Group 3 are classified in class 530, subclass 391.7. Thus, an immunoconjugate of Group 3 is a specific embodiment of the antibody claimed in Group 1. Accordingly, the monoclonal antibodies of Group 1 and the immunoconjugates of Group 3 are not distinct, and the criteria for requiring restriction of the Groups 1 and 3 has not been met.

The Office also states that the inventions of Groups 4-6 and 7 are distinct from each other. Applicants contend that the method of Group 7 is directed to inhibiting the growth of cells expressing PSCA. The methods of Groups 4-6 are directed to inhibiting the growth of cells expressing PSCA, such as prostate, bladder and pancreatic carcinomas. Furthermore, the Office states that the claims of Groups 4-6 and 7 are classified in class 424, and Groups 4-6 are classified in subclass 183.1, and Group 7 is classified in subclass 156.1. Therefore, the methods of Groups 4-6 are specific embodiments of the claims in Group 7. Thus, the claims in Groups 4-6 and 7 are not distinct. Accordingly, the criteria for requiring restriction of the claims in Groups 4-6 and 7 has not been met.

Additionally, the Office states that the inventions of Groups 8-11 are distinct from each other. Applicants contend that the methods of Groups 8-11 are directed to methods for treating a subject having a cancer, such as prostate cancer, bladder cancer and pancreatic cancer. Furthermore, the claims of Groups 8-11 are classified in class 424, subclass 183.1. Thus the claims in Groups 8-11 are not distinct. Accordingly, the criteria for requiring restriction of the claims Groups 8-11 has not been met.

The Office states that Groups 4-11 are distinct from each other. The Office also states that Groups 4-11 are classified in class 424. Thus the claims in Groups 4-11 are not distinct. Accordingly, the criteria for requiring restriction of the claims in Groups 4-11 has not been met.

The Office states that the inventions of Groups 9 and 10 are distinct from each other and are distinct from the inventions of Groups 5-8 and Group 11. Applicants contend that the methods for treating a subject susceptible to or having a cancer involves the use of the antibodies of Groups 1, 5, and/or 8. Furthermore, the administered antibodies will inhibit the growth of cells expressing PSCA, thereby treating the subject susceptible to or having a cancer. Accordingly, the criteria for requiring restriction of the claims in Groups 9 and 10 has not been met.

Applicants respectfully contend that the second requirement of §803 has not been met. The Patent Office has not demonstrated a serious burden for searching the art. Each of the claims of Groups 1 and 3 are classified in the same class, and Groups 4-11 are classified in the same class. Furthermore, the claims of Groups 3-11 are either further embodiments of the monoclonal antibodies in Group 1, or use the antibodies of Group 1. Therefore, the art with respect to the claims in Groups 1 and 3-11 overlap because each of the claims in these Groups are related to the antibodies of Group 1. The Examiner can perform a search on the entire application without serious burden. Thus, search of the art with regard to the invention of Groups 1 and 3-11 would not place an undue burden on the Examiner. Moreover, separate prosecution of these claims would be unnecessarily duplicative and thus wasteful of Patent Office resources. Therefore, under MPEP Section 803, the instant claims do not require restriction.

Applicants respectfully request that the Examiner reconsider and withdraw the Restriction Requirement as these claims.

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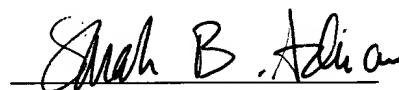
Conclusion

Applicants submit that claims 1-68 should properly be examined together for the reasons discussed above.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. If any fee is necessary, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,



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